REMARKS

This amendment is submitted in response to the final Office Action mailed on March 10, 2005. Claims 30, 32, 35 and 37-41 are pending in this application. Claims 33-34 have been withdrawn previously. In the Office Action, Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112, first paragraph, Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112, second paragraph and Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103. In response Claim 30 has been amended. This amendment does not add new matter. In view of the amendment and/or response set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Patent Office alleges that the specification fails to teach a skilled physiologist how to use protein hydrolysates and amino acids to promote "recovery" of an organ.

Applicants respectfully disagree and submit that one having ordinary skill in the art would be able to make or use the present claims based on the Applicant's specification without undue experimentation. For example, the specification provides adequate guidance to one of ordinary skill in the art on how to use protein hydrolysates and amino acids to promote "recovery" of an organ.

Applicants respectfully submit that there exists a correlation between rate of protein synthesis and promoting organ recovery. Currently, proteins, hydrolysates and free amino acids are used to meet the general needs of patients with intestinal diseases or conditions. See, specification, page 1, lines 9-19. However, these methods do not use proteins of varying degrees of hydrolysis to target specific bodily organs. Furthermore, various natural and synthetic peptides exist for targeting recovery of specific bodily organs. However, these peptides are not dietary protein and cannot serve as a primary protein source in nutritional formulas. See, specification, page 2, lines 8-20. Consequently, the advantage of the present claims is to promote recovery of specific organs using proteins of varying degrees of hydrolyzed, and/or free amino acids that are dietary protein and can serve as a primary protein source.

Applicants respectfully submit that the specification does not teach or suggest that the claimed invention can treat diseases such as hepatitis, cirrhosis of the liver and kidney infection as alleged by the Patent Office. Rather, the specification clearly states that feeding hydrolyzed

proteins alone, or in combination with free amino acids to patients suffering from illnesses or damage to the intestine can promote recovery of the intestine. See, specification, page 8, lines 17-24.

Applicants note the results showing that, depending on the degree of hydrolysis, hydrolyzed proteins and/or free amino acids promote recovery of the intestine. For example, the results show that Feed 4, composed of hydrolysates having degree of hydrolysis of about 35%, lead to increased protein concentration, RNA concentration, protein synthesis rate, daily protein synthesis and ribosomal efficacy in the duodenum. See, specification, page 22, lines 1-6. Additionally, though lipid and mineral contents per feed vary slightly, the significant variable in the five feeds is the degree of hydrolysis, where Feeds 1 and 5 are composed of intact proteins and free amino acids respectively, and Feeds 2, 3 and 4 are composed of hydrolysates with degree of hydrolysis of 14%, 17.3% and 35%. Similar to a normal, healthy person, rats with positive nitrogen balances, would generally receive whole proteins. See specification, page 1, lines 20-28. Consequently, Feed 1 of whole proteins can serve as the control. Furthermore, though the claims are drawn to promoting the recovery of organs, increased relative body weights of the tested rats, similar to rate of protein synthesis, for example, show the positive results of nutritional formulas composed of hydrolysates and/or free amino acids. See, specification, page 17, lines 5-10.

Further, Applicants respectfully disagree with the Patent Office's assertion that undue experimentation is required to practice the claimed invention. As stated above, protein hydrolysates and free amino acids can stimulate recovery of damaged organs. However, existing methods promote recovery by generally medicating rather than targeting specific organs. Applicants' present claims meet this need through results showing that, depending on the degree of protein hydrolysis, different feeds compositions target specific organs. Based on these results, all a skilled artisan would need to do is (1) identify the damaged or ill organ (e.g. targeted gastrointestinal tract), (2) select the appropriate feed composition to target that specific organ based on degree of protein hydrolysis, and (3) incorporate that feed composition within a nutritional formula. Numerous examples of such foodstuffs and amounts to be fed are given the specification. Consequently, one having ordinary skill in the art would be able to make or use the present claims based on the Applicant's specification without undue experimentation.

Based on at least these noted reasons, Applicants believe that Claims 30, 32, 35 and 37-41 fully comply with 35 U.S.C. §112, first paragraph. Accordingly, Applicants respectfully

request that the rejection of Claims 30, 32, 35 and 37-41 under 35 U.S.C. §112, first paragraph, be withdrawn.

In the Office Action, Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Specifically, the Patent Office alleges that, although the claims are drawn to a method of promoting "recovery" of an organ, it is unclear what the organ is recovering from.

Applicants respectfully submit that, as disclosed in the specification, the claimed invention promotes the recovery of an organ from disease or condition. The claimed invention can treat, for example, premature babies with underdeveloped intestines (condition), elderly people with intestinal atrophy (condition), Crohn's disease, severe diarrhea (disease) and colitis (disease). See, specification, page 8, lines 8-28. The specification discloses recovery of organs from the examples above and diseases and conditions similar to the examples above.

Based on at least these noted reasons, Applicants believe that Claims 30, 32, 35 and 37-41 fully comply with 35 U.S.C. §112, second paragraph. Accordingly, Applicants respectfully request that the rejection of Claims 30, 32, 35 and 37-41 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Nakamura (*J. Dairy Sci.* 78(6) 1253-1257, 1995) ("*Nakamura*") or Masuda (*American Institute of Nutrition* 126(12) 3063-3068, 1996) ("*Masuda*"). Applicants believe these rejections are improper and respectfully traverse them for at least the reasons set forth below.

Applicants respectfully submit that *Nakamura* and *Masuda* fail to disclose or suggest all the claimed elements. Specifically, both cited references fail to disclose or suggest, as required by the claims, a method for promoting recovery of a specific organ of a mammal. Though both references disclose using hydrolysates from sour milk to combat hypertension, neither reference discloses any results indicating any further benefit or, specifically, any benefit to a specific organ.

In the Office Action, Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 5,166,132 to Gordon ("*Gordon*") or U.S. Patent No. 5,313,873 to Tomita ("*Tomita*"), and as being unpatenable over *Gordon* or *Tomita* in view of

U.S. Patent No. 6,645,942 to Verna ("*Verna*"). Applicants believe these rejections are improper and respectfully traverse them for at least the reasons set forth below.

Applicants have amended Claim 30 to recite, in part, a method for promoting recovery of a specific internal organ of a mammal, the method comprising the steps of: selecting a form of a dietary milk protein hydrolysate which increases protein concentration or rate of protein synthesis in the specific organ; and internally administering a therapeutically effective amount of the dietary milk protein hydrolysate to the mammal. This amendment is supported in the specification, for example, at page 9, lines 1-8. Based on this amendment, *Gordon* and *Tomita* fail to disclose or suggest the internal administering of a milk protein hydrolysate as required by the present claims. Instead, the references, in attempting to heal hair and/or skin maladies, apply the hydrolysate topically to the surface of the skin or hair. See, *Gordon,* column 3, lines 4-10; *Tomita,* Abstract. Consequently, the cited references fail to address the recovery of internal organs.

In the Office Action, Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 6,645,942 to Smith ("*Smith*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Applicants respectfully submit that *Smith* does not disclose or suggest all of the claimed elements. As stated above, prior art discloses that the absorption of protein hydrolysates serves the general amino acid needs of patients. However, the prior art fails to disclose a method for promoting specific organ recovery. *Smith* also fails to disclose or suggest a similar method, as required by the present claims. The Patent Office states the same. See, Office Action, page 10, lines 10-12. Rather, *Smith* discloses a "growth promoting activity" similar in effect to growth hormone, further exemplified by the preferred delivery mode – a food or drink product as an infant formula or animal feed. See, *Smith*, page 10, lines 14-23. Lastly, *Smith* fails to disclose that varying the degree of hydrolysis causes preferential absorption, synthesis and use of a protein as a macronutrient.

In the Office Action, Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 4,716,151 to Jolles ("*Jolles*"). Applicants believe these rejections are improper and respectfully traverse them for at least the reasons set forth below.

Applicants respectfully submit that *Jolles* fails to disclose or suggest all of the claimed elements. For example, *Jolles* fails to disclose or suggest, as required by the claims, a method for promoting a specific organ recovery. Rather, *Jolles* discloses a non-specific

immunostimulant promoting immunity against infection. See, *Jolles*, column 2, lines 5-12. Here, "non-specific" means "a general purpose or effect," rather than a specific purpose against a specific organ. See, *Merriam-Webster's Medical Dictionary (2002).*

In the Office Action, Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 5,679,771 to Ballard ("*Ballard*") in view of U.S. Patent No. 5,661,123 to Stalker ("*Stalker*"). Applicants believe these rejections are improper and respectfully traverse them for at least the reasons set forth below.

Applicants respectfully submit that the cited references fail to disclose or suggest all the claimed elements. *Ballard* fails to disclose or suggest, as required by the claims, a method of using dietary milk protein hydrolysates to promote specific organ recovery. The Patent Office states the same. See, Office Action, page 11, lines 18-19. Likewise, *Stalker* fails to disclose or suggest the same method. While *Stalker* does disclose the use of milk protein hydrolysates to treat patients with elevated protein needs, it fails to disclose targeting specific organs. Furthermore, *Stalker* does not disclose altering the degree of milk protein hydrolysis to target specific organs. This is a unique aspect of Applicants' present claims and is supported in Claim 30 ("selecting a form of dietary milk protein hydrolysate which increases... rate or protein synthesis in the specific organ") and the specification. See, specification, page 5, lines 3-30.

In the Office Action, Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Qu, Zhensheng (*Journal of Nutrition* 126(4) 906-912, 1996) ("*Qu*") in view of *Stalker*. Applicants believe these rejections are improper and respectfully traverse them for at least the reasons set forth below.

Applicants respectfully submit that the cited references fail to disclose or suggest all the claimed elements. For example, *Qu* fails to disclose or suggest, as required by the claims, the use of hydrolyzed milk proteins. The Patent Office states the same. See, Office Action, page 13, lines 10-11. Furthermore, though *Qu* treated rats with varying concentrations of dietary protein, *Qu* fails to disclose or suggest varying the degree of protein hydrolysis. See, *Qu*, page 907, column 1, lines 8-13. Similarly, *Stalker* fails to disclose or suggest, as required by the claims, altering the degree of milk protein hydrolysis to target one organ versus another, which is a unique aspect or Applicants' present claims and is supported in Claim 30 and the specification. See, specification, page 5, lines 3-30.

In the Office Action, Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 5,723,446 to Gray ("*Gray*"). Applicants believe these rejections are improper and respectfully traverse them for at least the reasons set forth below.

Applicants respectfully submit that the *Gray* fails to disclose or suggest all the claimed elements. *Gray* fails to disclose or suggest, as required by the claims, varying the degree of protein hydrolysis to target specific organ recovery. Although *Gray* does disclose various embodiments with different percentages of hydrolyzed casein and whey proteins, *Gray's* experiment only tests a whole protein formula versus a single hydrolyzed protein formula. See, *Gray,* column 6, lines 22-38. Consequently, *Gray* fails to establish varying organ performance due the varying degrees of milk protein hydrolysis.

In the Office Action, Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over *Gray* in view of U.S. Patent No. 6,001,878 to Van Leeuwen ("*Van Leeuwen*"), and as being unpatentable over *Gray* in view of U.S. Patent No. 5,981,590 to Panigrahi ("*Panigrahi*"). Applicants believe these rejections are improper and respectfully traverse them for at least the reasons set forth below.

Applicants respectfully submit that the cited references fail to disclose or suggest all the claimed elements. As stated above, *Gray* fails to disclose or suggest varying the degree of protein hydrolysis to target specific organ recovery. *Van Leeuwen* and *Panigrahi* fail to disclose or suggest the administration of hydrolyzed milk proteins at all. The Patent Office states the same. See, Office Action, page 15, lines 2-3 and 15-16. As a result, *Van Leeuwen* and *Panigrahi* also fail to disclose or suggest varying the degree of milk protein hydrolysis to target specific organ recovery, as required by the present claims.

In the Office Action, Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Boza, Julio (*Journal of Pediatric Gastroenterology and Nutrition* 22(2) 186-193, 1996) (*"Boza"*). Applicants believe these rejections are improper and respectfully traverse them for at least the reasons set forth below.

Applicants respectfully submit that *Boza* fails to disclose or suggest all the claimed elements. *Boza* fails to disclose or suggest, as required by the claims, varying the degree of milk protein hydrolysis to target specific organ recovery. *Boza* concludes that intact whey proteins and hydrolyzed whey proteins are both suitable for recovery from malnutrition. See, *Boza,* page 92, column 2, lines 40-45. However, *Boza* could not make any further conclusions regarding the effectiveness of hydrolyzed whey proteins versus intact whey proteins. Furthermore, *Boza* limits

its research to recovery from malnutrition, and not specific organ recovery through varying degrees or milk protein hydrolysis. As a result, *Boza* is not related to the growth or recovery of a specific organ and fails to disclose that a specific organ can be targeted with a milk protein hydrolysate having a pre-determined degree of hydrolysis. This aspect, missing from *Boza*, is unique to Applicants' present claims, as supported in the claims and specification.

Accordingly, Applicants respectfully request that the obviousness rejections with respect to Claims 30, 32, 35 and 37-41 be reconsidered and the rejections be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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